UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/032,191	12/21/2001	Philippe Collas	50195/003002	4902

21559 7590 01/11/2005

CLARK & ELBING LLP
101 FEDERAL STREET
BOSTON, MA 02110

EXAMINER	
WOITACH, JOSEPH T	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/032,191	COLLAS ET AL.	
	Examiner	Art Unit	
	Joseph T. Woitach	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 October 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 4-53* is/are pending in the application.

4a) Of the above claim(s) *16-42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 43-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This application filed January 9, 2002, claims benefit to provisional application 60/258,151, filed December 22, 2000.

Applicants' amendment filed October 15, 2004, has been received and entered. Claims 2 and 3 have been cancelled. Claims 1, 4-6, 8, 9, 14 have been amended. Claims 43-53 have been added. Claims 1, 4-53 are pending.

Election/Restriction

Applicant's election without traverse of Group I was acknowledged. Newly added claims 43-53 are drawn to the elected invention and will be included in the examination.

Claims 1, 4-53 are pending. Claims 16-42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse. Claims 1, 4-15 and 43-53 drawn to a method of cloning a non-human mammal comprising incubating a permeabilized cell in a reprogramming media to form a reprogrammed cell are currently under examination.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Objections

Claims 51 and 52 are objected to because of the following informalities: reference to step (b) recited in the claims appears to be incorrect because the step of inserting in claim 1 has been amended to be step (c).

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Newly amended claims 1, 4-15, 43-53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The final Written Description Examination guidelines that were published on January 5, 2001 (66 FR 1099; available at http://www.uspto.gov/web/menu/current.html).

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111 (Fed. Cir. 1991), clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d at 1117. The specification does not "clearly allow persons of ordinary skill in the art to

recognize that [he or she] invented what is claimed."*Vas-Cath Inc. v. Mahurkar*, 19USPQ2d at 1116. In the instant case, a writtten description for a mitotic cell extract, in particular one that is capable of reprogramming the permeabilized cell, lacks written description. Specific recitation of the embodiment can be found in the specification at page 16, line 12, and here the specification teaches that a mitotic cell extract can be an example of a "mitotic reprogramming media" "(e/g., a mitotic cell extract) that induces chromatin condensation and nuclear envelope breakdown", however a review of the specific teachings in the specification do not clearly describe the structurally elements of this mitotic cell extract or the relevant methods required to practice the method as broadly claimed. Again, is noted the literal support for the amendment is only as an example and review of the specification does not describe or support the breadth of any cell extract to provide for the removal or addition of "a factor" that would result in a recipient oocyte that develops into a fetus. Mitotic is a broad term encompassing any part of the mitotic cell cycle, and extract is broad encompass any and all types of extraction procedures. There is no specific guidance nor description of the requirements of any specific extract that cold be used successfully in the instantly claimed method.

The claimed invention as a whole is not adequately described if the claims require essential or critical elements which are not adequately described in the specification and which are not conventional in the art as of Applicants effective filing date. Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics (as it relates to the claimed invention as a whole) such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. *Pfaff v. Wells Electronics, Inc.*, 48 USPQ2d

1641, 1646 (1998). In the instant case, Applicants have amended the claims to recite a general example that has literal support in the specification, however have failed to provide any specific description of this embodiment that would be functional in the context of the claimed method. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of identifying it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 (Fed. Cir. 1991).

Applicants attention is drawn to the decision of *The Regents of the University of California v. Eli Lilly and Company* (CAFC, July 1997) wherein it was stated:

In claims involving chemical materials, generic formulas usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate written description of the claimed genus. In claims to genetic material, however, a generic statement such as "vertebrate insulin cDNA" or "mammalian cDNA," without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. See *Fiers,* 984 F.2d at 1169-71, 25 USPQ2d at 1605-06 (discussing *Amgen*). It is only

a definition of a useful result rather than a definition of what it achieves as a result. Many such genes may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. *See In re Wilder*, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence. In the instant case, the recitation of a general example provided in the specification does not provide adequate description of the extract that is functional in the claimed methods, thus the rejected claim fails to meet the written description requirement under 35 U.S.C. 112, first paragraph.

Claims 45-50 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. 37 CFR 1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application".

Specifically, the specific concentrations, times and temperatures are set forth in examples and are supportive for use at most with the specific cell and other conditions taught in the example.

To the extent that the claimed compositions and/or methods are not described in the instant disclosure, claims 45-50 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, since a disclosure cannot teach one to make or use something that has not been described.

MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. In re Rasmussen, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application. MPEP 2163.06 further notes "When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. Applicant should therefore specifically point out the support for any amendments made to the disclosure" (emphasis added).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
> (f) he did not himself invent the subject matter sought to be patented.

Claims 1, 4-15 rejected under 35 U.S.C. 102(e) as being anticipated by Robl *et al.* (2004/0068760) is withdrawn.

As indicated by Applicants, review of the priority documents demonstrates that the first disclosure of the claimed information does not proceed the filing date of the instant application, therefore, the reference does not qualify as a 102(e) type reference.

Claims 1, 4-15 rejected under 35 U.S.C. 102(e) as being anticipated by Collas *et al.* (2002/0142397 A1) is withdrawn.

As indicated by Applicants, the teachings of Collas *et al.* while detailing the same methods of reprogramming a cell does not set forth the specific steps of using the reprogrammed cell in methods of cloning animals.

Claims 1, 4-15 rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter is withdrawn.

As argued by Applicants and discussed above, the claimed inventions of Robl *et al.* and by Collas *et al.* (2002/0142397 A1) are different from that instantly claimed.

Claims 1, 4-15 stand rejected and newly added claims 43, 51-53 are rejected under 35 U.S.C. 102(e) as being anticipated by Chapman (US Patent Pub. No. 2002/0001842 A1).

Applicants note that the present claims have been amended to encompass the use of a cell that "comprises pores in the plasma memebrane or partial, but not complete, removal of its plasma memebrane" (top of page 16 of Applicants amendment), and that though Chapman teaches to reprogram a cell by dedifferentiating it by the introduction of cytoplasm and cloning animals by general methodology known in the art, Chapman fails to teach methods that exploit the use of a permeabilized cell. See Applicants' amendment, page 16. Applicants' arguments have been fully considered, but not found persuasive.

Initially it is noted that the claim 1 has been amended to recite a "cell comprising pores in its plasma membrane or a partial plasma memebrane" (see claim 1(a)) and not specfically "comprises pores in the plasma memebrane or partial, but not complete, removal of its plasma memebrane" as indicated in Applicants' arguments. The use of comprising is broad and open to reasonable interpretation provided by the specification or recognized in the art. In this case the specification supports that a permeabilized cell includes a cell with the plasma membrane completely removed. Further, the methods of Chapman of injection with a needle form a pore through which the cytoplasm is delivered. The only methods known in the art for cloning animals from a differentiated cell require nuclear transfer into an oocyte as set forth in steps c and d of claim 1 of the instantly claimed method. Claims 43, 51-53 simply set forth the methods

steps for performing nuclear transfer. As noted previously, Chapman teaches a method wherein a cell is de-differentiated by the introduction of cytoplasm from a more primitive cell (see summary in abstract). Chapman teaches that the reprogrammed cell can be made and used in nuclear transfer methodology to result in cloned animals (columns 1-3).

Claims 1, 7 and 9-15 stand rejected and newly added claims 43, 51-53 are under 35 U.S.C. 102(e) as being anticipated by Machatay *et al.* (US Patent 6,211,429).

Applicants note that the present claims have been amended to encompass the use of a cell in which the plasma membrane is still at least partially intact, and that the methods of nuclear transfer using an isolated nuclei as taught by Machatay et al. would not anticipate the method as amended. See Applicants' amendment, page 16. Applicants' arguments have been fully considered, but not found persuasive.

As discussed above, claim 1 has been amended to recite a "cell comprising pores in its plasma membrane or a partial plasma memebrane" (see claim 1(a)) and not specfically "comprises pores in the plasma memebrane or partial, but not complete, removal of its plasma memebrane" as indicated in Applicants' arguments. The use of "*comprising*" is broad and open to reasonable interpretation provided by the specification or recognized in the art. In this case the specification supports that a permeabilized cell includes a cell with the plasma membrane completely removed. The present claims broadly encompass providing an isolated nucleus to an oocyte, and using said resulting cell to produce a cloned fetus. As such, the present methods encompass nuclear transfer methodology. Machatay *et al.* teach the activation of an oocyte for application in nuclear transfer methodology. It is taught that the nucleus of a cell can be isolated

by a variety of methods by methods known and used in the art (see for examples bridging columns 9-10). Additionally, the methods steps of newly added claims 43, 51-53 are routine method steps in the practice of nuclear transfer methodology, and thus anticipated by the methods taught by Machatay *et al.*

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 4-15 stand and newly added claims 43-53 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of copending Applications Robl *et al.* (2004/0068760) and Collas *et al.* (2002/0142397 A1).

Applicants do not discuss the specific merits of the rejection and request to hold the rejection in abeyance until allowable subject matter is indicted. See Applicants amendment, page 18.

Applicants' request is noted, however a rejection can not be held in abeyance and no allowable subject matter has been indicted.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claim is allowed. Claims 44-50 are free of the art of record because while streptolysin O was a known bacterial toxin agent, there is no specific motivation in the art of record to permeabilize a donor cell with this agent in nuclear transfer methodology.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (571)272-0734.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571)272-0532.

Joseph T. Woitach

Joe Woitach
AU1632